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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,200	07/02/2001	Daniel H. Cohn	18810-81553	5628

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PERKINS COIE LLP
POST OFFICE BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
SITTON, JEHANNE SOUAYA	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,200	COHN ET AL.	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *109-113,115,117-120 and 151-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109-113,115,117-120 and 151-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 109-113, 115, 117-120 and 151-153 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The Declaration submitted 1/16/2004, under 37 C.F.R. 1.132 was sufficient to overcome the rejection under 35 USC 102(a) made in section 8 of the previous office action.

Maintained Rejections

Claim Rejections - 35 USC § 102

4. Claims 109, 115 and 117-120 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurima et al (hereinafter referred to as Kurima; PNAS, vol. 95, pp 8681-8685, July 1998).

Kurima teach the nucleotide sequence of murine SK2, which is 85.6% identical to SEQ ID NO: 1 over nucleotides 92-1924 (see attached sequence alignment). As the claims do not recite an upper or lower length limitation or what constitutes a PAPSS2 specific nucleic acid sequence or a "PAPSSE gene specific fragment", the nucleotide sequence of murine SK2 anticipates the nucleic acids of claims 109-113 and 115. Further, Kurima teaches nucleic acid primers for amplification (see p. 8682, 2nd col. First full para) which contain sequences

complementary (albeit not the full complement) to the claimed nucleic acids. Such sequences have been broadly interpreted to encompass "PAPSS2 specific" sequences.

Response to Arguments

5. The response traverses the rejection. The response asserts that the claims have been amended to delete the recitation of "gene specific fragment". It is noted that this recitation has not been deleted from claim 17. The response asserts that that amended claims 115 and 118-120 are directed to PAPSS2-specific fragments of SEQ ID NOS 3, 5-6, 11-18, and 18 at least 15 nucleotides long. This argument was not found persuasive. The response appears to be arguing that the fragments must be 15 contiguous nucleotides from the recited SEQ ID NOS. However, the claims do not recite this limitation. The limitation set forth in those claims with regard to length has been broadly interpreted to encompass that the primers and probes claimed must be at least 15 nucleotides long, not that they contain fragments comprising 15 or more contiguous nucleotides of the recited SEQ ID NOS. The response further asserts that the specification defines PAPSS2 as a human PAPSS2 nucleotide sequence of SEQ ID NO: 1. This argument has been thoroughly reviewed but was found unpersuasive. The section of the specification that is being referred to in the response does not actually define PAPSS2 to be any specific sequence. In other words, PAPSS2 has not been defined as SEQ ID NO: 1. The specification sets forth preferred embodiments for PAPSS2 but these embodiments only serve to exemplify what sequences would read on the claims and are not the definition of PAPSS2. If it were, the terms PAPSS2 and SEQ ID NO 1 would be the exact same thing and any PAPSS2 specific fragment could only mean contiguous sequences from SEQ ID NO 1, which from the construction of the claims, is not the case. Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, even if all the claims were drawn to "human" sequences as in claim 109 section D which recites language to a human polypeptide, the recitation of "human" fragment does not/would not carry any weight because the origin of the nucleic acid does not change its structure. Additionally, the specification has not defined what sequences other than the full sequence of SEQ ID NO: 1, would be considered a 'human' sequence or how to distinguish such over 'non human' sequences. For these reasons and the reasons made in the previous office action, the rejection is maintained.

Claim Rejections - 35 USC § 103

6. Claims 151-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurima, in view of Ahern (The Scientist, vol. 9, 1995, pages 1-5 from the internet).

Kurima teach the nucleotide sequence of murine SK2, which is 85.6% identical to SEQ ID NO: 1 over nucleotides 92-1924 (see attached sequence alignment). As the claims do not recite an upper or lower length limitation or what constitutes a PAPSS2 specific nucleic acid sequence, the nucleotide sequence of murine SK2 anticipates the nucleic acids of claims 109-113 and 115. Further, Kurima teaches nucleic acid primers for amplification (see p. 8682, 2nd col. First full para) which contain sequences complementary (albeit not the full complement) to the claimed nucleic acids. Such sequences have been broadly interpreted to encompass "PAPSS2 specific" sequences.

Kurima does not teach the primer pairs in kit format, however Ahern teaches that packaging biochemical reagents in kit format save the researcher time and provides convenience

(see p. 4, para 1-2). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the primer pairs of Kurima in kit format, as taught by Ahern, for the purpose of making the method of Kurima easier and more convenient to perform. The ordinary artisan would have been motivated to package the primer pairs in kit format as Ahern teaches that packaging reagents in kit format offer scientists the opportunity to better manage their time.

Applicant should note that the instructions for use in the kit carry no patentable weight.

Response to Arguments

7. The response traverses the rejection with the same arguments used for the 102(b) rejection over Kurima, set forth above. For the reasons set forth in section 5, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. Claims 109-113, 115, 117-120 and 151-153 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acid sequences, primer pairs, and kits comprising such. The recitation of nucleic acid sequences "comprising", "gene specific fragments", and "PAPSS2 specific nucleic acids" encompasses an extremely large number of genomic sequences, mutants, variants, and homologs of human PAPSS2 which have not been taught or described in the

specification. The specification teaches the sequence of SEQ ID NO 1, which is the sequence of human PAPSS2. The claims, however, only recite sequences from within SEQ ID NO: 1, wherein sequences "comprising", "gene specific fragments" and PAPSS2 specific fragments of this minimal recitation of contiguous nucleotides within SEQ ID NO 1 or SEQ ID NOS 3-6, 11-18 and 28 encompass genomic sequences, as well as mutants, variants and homologs of human PAPSS2 which have not been taught or described by the specification. The specification does not define the term "PAPSS2" such that the skilled artisan would be able to determine what constitutes a PAPSS2 specific nucleic acid. These recitations, along with the terms "comprising" and "gene specific fragments" encompass a large genus of nucleic acids. However, the disclosure of the human and mouse PAPSS2 cDNA represent a species of this extremely large genus of nucleic acids and is not representative of this large genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 1, 3-6, 11-18, and 28, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25

USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to Arguments

9. The response traverses the rejection. The response asserts that the claims have been amended to delete the recitation of 'gene specific fragment'. It is noted however, that claim 17 continues to recite this phrase. With regard to claim 109, the response asserts that the claim has been amended to nucleotide sequences which are fragments of SEQ ID NO: 1. This is argument was not found persuasive because the claim still recites "a nucleic acid segment encoding a 'human' PAPPSS2 protein having 'an' amino acid sequence of SEQ ID NO: 7". The term 'having' is not considered closed terminology. Further, the specification has not defined what the specific construction of a sequence is for it to be considered a 'human' sequence or a human

fragment. Additionally, the specification has not defined what is meant by a PAPSS2 sequence. The response asserts that the specification defines PAPSS2 as a human PAPSS2 nucleotide sequence of SEQ ID NO: 1. This argument has been thoroughly reviewed but was found unpersuasive. The section of the specification that is being referred to in the response does not actually define PAPSS2 to be any specific sequence. In other words, PAPSS2 has not been defined as SEQ ID NO: 1. The specification sets forth preferred embodiments for PAPSS2 but these embodiments only serve to exemplify what sequences would read on the claims or the term and are not the definition of PAPSS2. If it were, the terms PAPSS2 and SEQ ID NO 1 would be the exact same thing and any PAPSS2 specific fragment could only mean contiguous sequences from SEQ ID NO 1, which from the construction of the claims, is not the case. The claims continue to encompass mutants, variants and homologs of human PAPSS2.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 120, 152, and 153 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim is confusing as it is not in proper Markush format. For example, it appears from the claim construction that the forward primer comprises any of the limitations of (A) as well as the limitations of (B) and (C), and the reverse primer comprises any of the limitations of (D) as well as the limitations of (E) and (F).

Claims 152 and 153 lack antecedent basis for the recitation of "the" pair of oligonucleotide primers. The claims are dependent from claims 117 and 120 respectively, which

recite more than one possible primer pair. Therefore, it is unclear which primer pair is being referred to in claims 152 and 153.

Claim Rejections - 35 USC § 102

12. Claims 109-113 and 115 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796; 12/1996).

The amended claims are drawn to nucleotide "a" sequence fully complimentary to SEQ ID NO: 1 or SEQ ID NOS: 3-6. As the claims do not recite any upper length limitations the claims encompass a large number of possible 10 mer nucleic acid sequences. Brennan teaches making every possible 10 nucleic acid sequence (see example 4, col. 9), many of which are encompassed by the instant claims as they would be themselves, fully complementary to regions with the designated SEQ ID NOS.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. No claims are allowable although allowable subject matter does exist. SEQ ID NO: 1 as well as sequences consisting of the sequence of any of SEQ ID NOS: 3-6, 11-18 and 28.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571) 272-0507.

Jehanne Sitton
Primary Examiner
Art Unit 1634
4/1/04